K011843

AUG 1 0 2001

ATTACHMENT 1

510(k) Summary Of Safety and Effectiveness Information Upon Which An Equivalence Determination Could be Made

Trade or Proprietary Name:	Genzyme Direct α-Amylase Test Reagent
Common or Usual Name:	Reagent for α-Amylase Test
Classification Name:	Amylase Test System
Establishment Name and Address	Genzyme Corporation One Kendall Square Cambridge, MA 02139-1562
Contact Person	Barbara Pizza, Manager, Regulatory Affairs (617) 252-7953

The use of the Genzyme Direct Amylase Reagent assay in the clinical laboratory setting is substantially equivalent to a currently marketed method for Roche Boehringer Mannheim α-Amylase/EPS for the diagnosis of Pancreatitis.

The Genzyme Direct Amylase Reagent is a quantitative method for the detection of α-amylase activity in serum and plasma.

PERFORMANCE STUDIES

Comparative Performance Studies

A Comparative performance study was conducted using the Genzyme Direct Amylase Reagent, and predicate method (Roche Boehringer Mannheim α-Amylase/EPS).

The slope, intercept, correlation coefficient, and sample range for this comparison is provided below.

	Direct Amylase vs. Roche Serum
Number of samples	50
Slope	0.90
Intercept (U/L)	-2.50
Correlation Coefficient (r)	0.9985
Sample Range (U/L)	28 - 304 (EPS)
Sample Range (U/L)	22 – 278 (Genzyme)

The Genzyme method yielded acceptable correlation with the predicate method for samples across the usable range of the product.

Linearity

Linearity studies demonstrated that the Direct Amylase assay is linear up to 2000 U/L.

Precision

Both within-run and between-run studies were performed. Testing was done using frozen serum pools at three target levels of α-amylase activity for within-run precision and between-run.

Within-Run

Each serum pool was tested 20 times in one batch using the Direct Amylase assay. The mean, standard deviation (SD) and coefficient of variation (%CV) were calculated for each serum pool.

Sample	1	2	3	4
N	20	20	20	20
Mean (U/L)	61	272	902	1509
%CV	1.34	0.61	0.51	0.62

The Direct Amylase assay yielded excellent within-run precision with CVs of ≤ 2.0%.

Between-Run

Each serum pool was tested in duplicate, twice per day, for at least five days using the Direct Amylase assay for a total of 40 determinations. The mean, SD and %CV were calculated for each pool as follows:

Sample	1	2	3	4
n	40	40	40	40
Mean (U/L)	60	273	917	1507
%CV	1.7	0.8	0.9	0.6

The Direct Amylase assay yielded excellent between-run precision with CVs ≤ 2.0%.

Interference Studies

The effects of interfering substances was evaluated by adding varying levels of potential interferents to a specimen pool. These determined that lipemia, triglyceride, ascorbic acid, bilirubin, hemoglobin and glucose did not interfere with the performance of the Genzyme Direct Amylase assay at the levels up to and including those indicated below.

Interfering Substance	Concentration
Liposyn	3000 mg/dL (1%)
Triglyceride	3000 mg/dL
Ascorbic Acid	50 mg/dL
Bilirubin (unconjugated)	50 mg/dL
Bilirubin (conjugated)	50 mg/dL
Hemoglobin	500 mg/dL
Glucose	2000 mg/dL

Conclusion

Based on the results of the studies described above, the Genzyme Direct Amylase Reagent assay is substantially equivalent in performance to the predicate method for quantifying α-amylase activity in serum and plasma.

In lieu of a 510(k) statement under 513(i) of the Act, this information is provided as a 510(k) summary for disclosure to any other persons/companies without the specific written authorization from Genzyme Corporation.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

AUG 1 0 2001

Ms. Barbara Pizza
Manager, Regulatory Affairs
Genzyme Corporation
One Kendall Square
Cambridge, MA 02139-1562

Re: 510(k) Number: K011843
Trade/Device Name: Direct Amylase Reagent
Regulation Number: 862.1070
Regulatory Class: Class II
Product Code: JFJ
Dated: June 11, 2001
Received: June 12, 2001

Dear Ms. Pizza:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

3.0 INTENDED USE

510(k) Number (if known): K011843

Device Name: Direct Amylase Reagent

Intended Use:

For the quantitative determination of α-Amylase activity in human serum or plasma.

NOTE: This is not changed from the original Premarket submission K933397.

Indications for Use:

Levels of serum and plasma α-amylase in patients have provided needed evidence for the diagnosis of acute pancreatitis.

For In Vitro Diagnostic Use.

NOTE: This is not changed from the original Premarket submission K933397.

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K011843

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X (Per 21 CFR 801.109) OR Over-The-Counter-Use ____ (Optional Format 1-2-96)